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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,233	12/12/2001	Jamey D. Marth	19452A-000130US	9630

20350 7590 11/30/2006

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EXAMINER
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SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/857,233

Applicant(s)

MARTH ET AL.

Examiner

David A. Saunders, PhD

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 August 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26,35-37 and 52-69 is/are pending in the application.
- 4a) Of the above claim(s) 63-67 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 57 is/are allowed.
- 6) ☒ Claim(s) 26 and 58-62 is/are rejected.
- 7) ☒ Claim(s) 35-37, 52-56, 68 and 69 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Amendment of 8/31/06 has been entered. Claims 26,35-37 and 52-69 are pending. Claims 26,35-37 and 52-62 and 68-69 are under examination. Claims 63-67 remain withdrawn.

The amendment has entered no new matter in the specification.

The amendment has entered no new matter in the claims.

The following corrections pertain to the previous Office action:

On PTO-326, under **Disposition of Claims**, at box 6 "2,35-37,52-58 and 68-696" should have read as -26,35-37,52-58,68 and 69--.

At page(s) 4, line 6 "102(b)" should have read as -102(a)--.

The amendment has overcome previously stated issues as follows:

The objection to Fig. 17.

The objection to the specification.

The rejection of claim 58 under 35 USC 112, 2<sup>nd</sup> paragraph.

The prior art rejection of claims 26, 35-37, 52-56 and 68-69 based upon Ellies et al. Applicant's provisional application 60/113,680 supports instant amended claim 26 (e.g. pgs 14-15 of '680).

The prior art rejection of claim 57 based upon Ellies et al. Applicant's provisional application 60/113,680 supports instant claim 57 (e.g. pg 33 of '680).

The prior art rejections based upon Fukuda, since Fukuda does not teach anything about a "mutation in a glycosyltransferase gene".

The following rejection is maintained.

Claim 58 is rejected under 35 U.S.C. 102(a) as being anticipated by Ellies et al.

Ellies et al were previously cited against base claim 57. While applicant's evidence that the Ellies et al article was not public ally available until 12/22/98 has overcome the rejection of claim 57 (due to support therefor in application 60/113,680

Art Unit: 1644

filed on 12/21/98), the evidence does not overcome the rejection of dependent claim 58. Claim 58 can be properly rejected for the embodiment in which a CD43 glycoform is detected by Ellies et al, because the claim encompasses more than merely detecting the CD43 glycoform. The claim also encompasses detecting a CD45 isoform; this embodiment is one which the examiner does not find to be supported by application 60/113,680. Claim 58 thus encompasses more than is supported by the '680 application and is properly rejected.

Since claim 26 is allowable over the rejections stated in the action of 5/30/06, claims 59-62 have been rejoined. Claims 63-67 remain withdrawn.

Claims 26-29 were previously rejected, in the action of 10/21/04, under 35 U.S.C. 102(a) as being anticipated by Bergmann et al.

Instant claims 59 and 61-62 correspond to previously pending claims 27-29.

Claim 60 does not correspond to any of previously rejected claims 26-29. It is, however, noted that CD22 inherently binds specifically to Sia6LacNac (spec. pg 30, lines 7-8 and pg 48, lines 29-30). Thus the CD22-Ig fusion protein of the prior art would have inherently specifically bound to Sia6LacNac.

No prior art rejection is presently stated, since the disclosure of Bergmann et al pertains to CDGS I A, which is associated with a mutation in a gene which encodes a phosphomannomutase, rather than a glycosyltransferase, as required by instant claim 26.

Claims 26 and 59-62 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specifically asserted utility or a well established utility.

As far as the examiner can determine, the only utility for/use of a diagnostic reagent which specifically binds Sia6LacNac, that could be ascertained by one of skill in the art, would be for the diagnosis of CDGS I A, as disclosed by Bergmann et al.

Art Unit: 1644

Applicant, however, has disclosed that CDGS I A is associated with a mutation in the PMM2 gene, which encodes a phosphomannomutase, rather than a glycosyltransferase (see spec. Pg 26, lines 27-31). Since instant claim 26 requires that one diagnose a disorder due to a deficiency in a glycosyltransferase there is a lack of scientific nexus between what is required by the method of claim 26 and what is detected in the method of dependent claims 59-62. Applicant has failed to point out how a deficiency in glycosyltransferase activity, due to a mutation, is related to any disorder which would be associated with a reduced level of Sia6LacNac.

Claims 26 and 59-62 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specifically asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

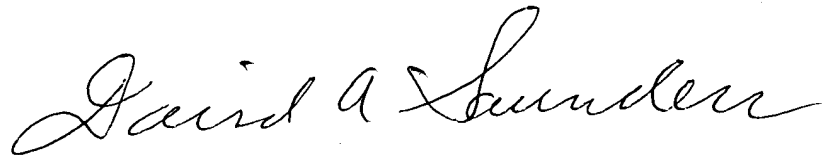
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1644

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 11/27/06 DAS

A handwritten signature in cursive script that reads "David A. Saunders". The signature is written in black ink and is positioned above the printed name and title.

DAVID A. SAUNDERS  
PRIMARY EXAMINER